REMARKS

Claims 1, 3, 5, 179-184, 186, 187, 189, 192, 193, 195, 201, 204-212, 222-227, 231-233, 241, 242, 244, 245, 250, 261-263, 276, 280-299, 303, and 305-308 are pending in this application. Applicants note that claims 1, 179, 181, 183, 184, 186, 187, 189, 192, 193, 195, 201, 204-212, 222-227, 231-233, 241, 242, 245, 250, 288-299, 303 and 305-307 have been deemed allowable. Claims 261-263, and 276 are canceled by this amendment, and claims 3 and 308 have been amended. Claim 3 has been amended to more particularly point out what Applicants regard as the invention. Support for the amendment to claim 3 is found in the specification *inter alia* at page 28, line 11. Support for the amendment to claim 308 is found *inter alia* in the specification in Table 2 at page 47. The amendments are fully supported by the specification of the present application and do not constitute new matter. Upon entry of this Amendment, claims 1, 3, 5, 179-184, 186, 187, 189, 192, 193, 195, 201, 204-212, 222-227, 231-233, 241, 242, 244, 245, 250, 280-299, 303, and 305-308 will be pending and under examination.

1. FORMALITIES

The Examiner has withdrawn claim 308 as directed to a nonelected invention. In response, Applicants have amended claim 308 to read on an isolated antibody comprising a CDR having an amino acid sequence of a VL CDR of the antibody P12F2, which is within the scope of Applicants' election in response to the February 20, 2002 election/restriction requirement issued in connection with the subject application. Accordingly, Applicants respectfully request that the Examiner reconsider her withdrawal of claim 308.

In paragraph four of the Office Action, the Examiner indicated that she has interpreted the phrase "amino acid sequence of SEQ ID NO" or "amino acid sequence of a VH CDR" as equivalent to "comprising SEQ ID NO." However, Applicants respectfully point out that the claims recite antibodies comprising a CDR variable domain that has a particular amino acid sequence. Thus, the claim language explicitly contemplates antibodies that comprise the sequence recited and not fragments of only the particular amino acid sequence.

In the June 4, 2004 Office Action, the Examiner requested courtesy copies of the statements by co-inventors Jeffry D. Watkins and Herren Wu which were previously

submitted by Applicants on April 21, 2004 in connection with a Petition for Correction of Inventorship Under 37 C.F.R. § 1.48(a). In response to the Examiner's request, Applicants enclose herewith courtesy copies of these statements, attached hereto as **Exhibit A**.

1. THE REJECTIONS UNDER 35 U.S.C. §101 SHOULD BE WITHDRAWN

The Examiner rejected claims 3, 5, 281, and 283 under 35 U.S.C. §101 as allegedly drawn to nonstatutory subject matter. In response, Applicants have amended claim 3 as suggested by the Examiner. Claim 3 now recites an "isolated" antibody. Applicants understand that claims 5, 281, and 283 were rejected because of their dependency on claim 3. Accordingly, Applicants respectfully assert that claims 3, 5, 281, and 283 satisfy the requirements of 35 U.S.C. §101 and respectfully request that the Examiner's rejection be withdrawn.

2. THE REJECTIONS UNDER 35 U.S.C. §112 SECOND PARAGRAPH SHOULD BE WITHDRAWN

The Examiner rejected claims 261-263, 276, 284, and 287 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In response to the rejection of claims 261-263 and 276 as depending from canceled claims, Applicants note that claims 261-263 and 276 have been canceled herein, rendering the rejection moot.

The Examiner also rejected claim 284 as allegedly unclear for reciting the phrase "a therapeutic or drug moiety." The Examiner alleged that the phrase lacks clarity because there is no indication of what these moieties are, or any associated therapeutic function.

In response, Applicants respectfully traverse the Examiner's rejection and maintain that claim 284 is clear and definite.

Claim 284 is directed to an antibody of the instant invention "wherein the antibody is conjugated to a therapeutic or drug moiety."

In reviewing a claim for compliance with 35 U.S.C. §112, second paragraph, the Examiner must analyze the claim in view of the specification, the prior art, and the interpretation that would be given by one of ordinary skill in the relevant art. M.P.E.P. §2173.02. When the specification states the meaning that a term is intended to have, the claim should be examined using that meaning. Id. at §2173.05(a).

Applicants respectfully assert that the meaning of the phrase "therapeutic or drug moiety" is clear and definite in view of the specification. For example, the specification at page 57, lines 4-19, provides that a "therapeutic moiety" is "a cytotoxin, *e.g.*, a cytostatic or cytocidal agent, a therapeutic agent or a radioactive metal ion, *e.g.*, alpha-emitters." The specification further lists numerous examples of specific cytocidal and therapeutic agents. The specification also describes what is meant by a "drug moiety" and provides specific examples of such moieties at page 57, lines 20-34. Applicants respectfully assert that in view of the specification combined with the knowledge in the art, one of skill would understand what is meant by the phrase "therapeutic or drug moiety" in claim 284. In the context of the specification and invention, it is clear that the "therapeutic or drug moiety" is for the treatment, prevention, or amelioration of an RSV infection. Accordingly, Applicants respectfully assert that claim 284 satisfies the notice requirement of 35 U.S.C. §112, second paragraph.

The Examiner also rejected claim 287 as allegedly unclear for recitation of the phrase "instructions for use" because the "use" is not identified in the claim.

In response, Applicants respectfully traverse the Examiner's rejection and maintain that claim 287 is clear and definite when properly construed in view of the specification.

Claim 287 is directed to an antibody of the instant invention "and instructions for use, in one or more containers."

The specification describes the use of the antibodies of the claimed invention, for example, at page 7, lines 30-33, which provides that the antibodies are used in methods for the "prevention, neutralization, treatment or amelioration of one or more symptoms associated with a RSV infection" comprising the administration of an antibody to a subject. The specification further provides examples of target serum concentrations for the antibodies

thus administered. See, for example, page 7, lines 34-51. Moreover, the specification provides numerous examples of dosages (see, e.g., page 9, lines 10-18) and methods of administration (see, e.g., page 65, lines 1-22). Accordingly, when the claims are properly construed in view of the specification as a whole, combined with the knowledge in the art, one of skill would understand what "use" is intended in claim 287. Accordingly, Applicants respectfully assert that claim 287 satisfies the notice requirement of 35 U.S.C. §112, second paragraph.

In summary, Applicants respectfully assert that claims 284 and 287 satisfy the requirements of 35 U.S.C. §112, second paragraph, and respectfully request that the Examiner reconsider and withdraw her rejection.

3. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

The Examiner rejected claim 180 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 10 of U.S. Patent No. 6,656,467 ("the '467 patent"). The Examiner stated that although the conflicting claims are not identical, they are not patentably distinct. The Examiner noted that SEQ ID NO:9 recited in claim 10 of the '467 patent is the same sequence as the SEQ ID NO:10 recited in instant claim 180 and that, lacking any structural differences, the properties of the antibodies are expected to be the same.

In response, Applicants note that they intend to file a terminal disclaimer in the subject application at such time as the claims are otherwise deemed in condition for allowance. Accordingly, Applicants respectfully request that the Examiner hold this rejection in abeyance until the claims have otherwise been deemed allowable.

4. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

The Examiner provisionally rejected claims 3, 180, and 182 as allegedly unpatentable over claim 153-158 of copending application U.S. Serial No. 09/996,288 under the judicially created doctrine of obviousness-type double patenting. The Examiner stated that although the claims are not identical, they are not patentably distinct from each other because claims 3, 180, and 182 of the instant invention is drawn to antibodies comprising SEQ ID NOS: 10, 19,

and 20, and the conflicting claims are directed to compositions comprising antibodies having the same sequences.

In response to the Examiner's provisional rejection, but without conceding the correctness thereof, Applicants will consider filing a terminal disclaimer in the application should the provisional rejection be converted to a non-provisional rejection pursuant to the terms of M.P.E.P. §804.

CONCLUSION

Applicants believe that the present claims meet all of the requirements for patentability. Entry and consideration of the foregoing amendments and remarks into the file of the subject application is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

Respectfully submitted,

Date: December 2, 2004

Margaret B. Brivanlou 40,922
For: Margaret B. Brivanlou (Reg. No.)

Jennifer J. Chheda 46,617
By: Jennifer J. Chheda (Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017-6742
(212) 901-9028

EXPRESS MAIL NO.: EV 335 858 849 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Young et al.

Application No.: 09/724,531

Filed: November 28, 2000

For: METHODS OF ADMINISTERING/DOSING ANTI-RSV ANTIBODIES FOR PROPHYLAXIS AND TREATMENT

Confirmation No. 7010

Group Art Unit: 1648

Examiner: Chen, Stacy

Attorney Docket No.: 10271-021

STATEMENT BY THE INVENTOR TO BE ADDED PURSUANT TO 37 C.F.R. §1.48 (a)(2)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Herren Wu, have reviewed and understand the content of the Petition for Correction of Inventorship Under 37 C.F.R. §1.48(a) submitted concurrently herewith to amend the above-identified application to correctly name all of the inventors. I hereby state that my name was inadvertently omitted, without deceptive intent, as a co-inventor of the currently claimed subject matter of the above-identified patent application. There was no deceptive intent on my part in the omission of my name as a co-inventor.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that I make these statements with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

4/21/04
Date

Herren Wu

1470704

EXPRESS MAIL NO.: EV 335 858 849 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Young et al.

Application No.: 09/724,531

Filed: November 28, 2000

For: METHODS OF ADMINISTERING/DOSING ANTI-RSV ANTIBODIES FOR PROPHYLAXIS AND TREATMENT

Confirmation No.: 7010

Group Art Unit: 1648

Examiner: S. Chen

Attorney Docket No.: 10271-021

STATEMENT BY THE INVENTOR TO BE ADDED PURSUANT TO 37 C.F.R. §1.48 (a)(2)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

I, Jeffry D. Watkins, have reviewed and understand the content of the Petition for Correction of Inventorship Under 37 C.F.R. §1.48(a) submitted concurrently herewith to amend the above-identified application to correctly name all of the inventors. I hereby state that I have no personal knowledge concerning the omission of my name as a co-inventor of the currently claimed subject matter of the above-identified patent application. There was no deceptive intent on my part in the omission of my name as a co-inventor.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that I make these statements with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

12/11/03
Date

Jeffry D. Watkins